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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,715	11/07/2001	Brent W. Weston	5470-259CT	8629

20792 7590 10/03/2003

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,715	WESTON ET AL.	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- Th MAILING DATE of this communication appears on the cover sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11,16-18 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *9-11,16-18 and 22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in claims 6, 7, 20 and 21 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Claims 9 and 16 specifically claim SEQ ID NOS: 1-24, which are targeted to and modulate the expression of either FUT3 or FUT6. Although the antisense sequences of SEQ ID NOS: 1-11 each target and modulate expression of the same gene, FUT3, and the and those of SEQ ID NOS: 12-22, each target and modulate expression of the same gene, FUT6, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of its gene, and each antisense, upon binding to its target, functionally modulates (increases or decreases) the expression of the gene and to varying degree. Furthermore, a search of more than one (1) of the antisense sequences claimed in said claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for

examination. Accordingly, applicants are required to elect one (1) antisense sequence from the above listed claims.

Furthermore, the targets of FUT3 and FUT6 are considered to be unrelated, since each has a unique structure, and is thought to behave uniquely according to its unique structure in its pathway. Since the oligos targeting these two genes are not disclosed as being used together, and because a search of for molecules that regulate two distinct genes present an undue burden on the Office to search these inventions in the same application, restriction is considered to be proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER

Attorney's Docket No. 5470-259CT PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Weston, et al.
Serial No.: To Be Assigned
Filed: Concurrent Herewith
For: ANTISENSE HUMAN FUCOSYLTRANSFERASE SEQUENCES AND METHODS OF USE THEREOF

Date: November 7, 2001

BOX PATENT APPLICATION
Commissioner for Patents
Washington, DC 20231

PRELIMINARY AMENDMENT

Sir:

Prior to the examination of the above application and calculation of claim fees, please amend the above-identified application as indicated below.

IN THE SPECIFICATION:

On page 1, line 9, please insert the following:

Cross-Reference to Related Applications

This application is a continuation of co-pending United States Application Serial No. 09/556,031, filed on April 20, 2000 (now allowed) which claims priority from U.S. Provisional Application Serial No. 60/131,068, filed April 26, 1999, the disclosures of which are incorporated by reference herein in their entirety.

IN THE CLAIMS:

Please cancel claims 1-8, 12-15 and 19-21.

Please amend Claim 9 as follows:

9. (Amended) A method of treating a subject afflicted with cancer, comprising administering to said subject an antisense oligonucleotide that hybridizes to a nucleic acid that encodes a fucosyltransferase, wherein said fucosyltransferase is selected from the group consisting of FUT3 and FUT6;

said oligonucleotide selected from the group consisting of oligonucleotides consisting of the sequence:

AGGCCATGGCAGGTTTCCTG (SEQ ID NO: 1);
AACTGAAGATCTACAAAAGA (SEQ ID NO: 2);
ACCAAGGTTCTGGAAAGAGA (SEQ ID NO: 3);
TGTAGGTCACCTGAGTGTGA (SEQ ID NO: 4);
GCTGCACCCAGGGGATCCAT (SEQ ID NO: 5);
TCTCGTAGTTGCTTCTGCTG (SEQ ID NO: 6);
GAGCGAGGCCGCAGCGTCTC (SEQ ID NO: 7);
ATCAGCCAGAACCATCACTC (SEQ ID NO: 8);
ACCTGTACCCTATAAGTGGT (SEQ ID NO: 9);
GATAACTTACCTGGAGAGGC (SEQ ID NO: 10);
TTAGGGTTGGACATGATATC (SEQ ID NO: 11);
CCCACTCCTGCAGGGCAGTG (SEQ ID NO: 12);
GGGTCTTCACCACTGGAGAG (SEQ ID NO: 13);
AGTGAAAAGGCTGACCTGAA (SEQ ID NO: 14);
TGGATGCCCGTGACACTGGG (SEQ ID NO: 15);
GCCGGGCCCAGGGGATCCAT (SEQ ID NO: 16);
CACCCAGATCCAGCGTCCCA (SEQ ID NO: 17);
ATCTCCTGACCTTGTGATCC (SEQ ID NO: 18);
GATCTCCTGACCTAGGAAGA (SEQ ID NO: 19);
TTCTCACTCAGTTGGCCCAT (SEQ ID NO: 20);
CCAACCACCACACCTGTCAT (SEQ ID NO: 21);
GGACGAGTAACAGCTGGATT (SEQ ID NO: 22);
GCTTGGCTGCACCCAGGGGATC (SEQ ID NO: 23);
CTCTGCCGCTCCTGGACACTGCTGC (SEQ ID NO: 24);

and continuous 15 or 18 nucleotide fragments of the sequences listed above in an amount effective to treat said cancer.

7. An oligonucleotide according to claim 1 selected from the group consisting of FUT6 antisense oligonucleotides having the sequence:

CCCACTCCTGCAGGGCAGTG (SEQ ID NO: 12);
GGGTCTTCACCACTGGAGAG (SEQ ID NO: 13);
AGTGAAAAGGCTGACCTGAA (SEQ ID NO: 14);
TGGATGCCCGTGACACTGGG (SEQ ID NO: 15);
GCCGGGCCCAGGGGATCCAT (SEQ ID NO: 16);
CACCCAGATCCAGCGTCCCA (SEQ ID NO: 17);
ATCTCCTGACCTTGTGATCC (SEQ ID NO: 18);
GATCTCCTGACCTAGGAAGA (SEQ ID NO: 19);
TTCTCACTCAGTTGGCCCAT (SEQ ID NO: 20);
CCAACCACCACACCTGTCAT (SEQ ID NO: 21); and
GGACGAGTAACAGCTGGATT (SEQ ID NO: 22).

8. A pharmaceutical formulation comprising an antisense oligonucleotide according to claim 1 in a pharmaceutically acceptable carrier.

9. A method of treating a subject afflicted with cancer, comprising administering to said subject an antisense oligonucleotide according to claim 1 in an amount effective to treat said cancer.

10. A method according to claim 9, wherein said cancer is a carcinoma.

11. A method according to claim 9, wherein said cancer is selected from the group consisting of colon, pancreatic, ovarian, gastric, breast, lung, hepatocellular, prostate, bladder, renal, and uterine cancer.

12. A nucleic acid encoding an antisense oligonucleotide that hybridizes to a nucleic acid that encodes a fucosyltransferase, wherein said fucosyltransferase is selected from the group consisting of FUT3 and FUT6.

Please amend Claim 16 as follows:

16. (Amended) A method of treating a subject afflicted with cancer, comprising administering to said subject a vector that comprises and expresses an exogenous nucleic acid encoding an antisense oligonucleotide that hybridizes to an endogenous nucleic acid that encodes a fucosyltransferase, wherein said fucosyltransferase is selected from the group consisting of FUT3 and FUT6 and wherein said nucleic acid is selected from the group consisting of:

AGGCCATGGCAGGTTTCCTG (SEQ ID NO: 1);
AACTGAAGATCTACAAAAGA (SEQ ID NO: 2);
ACCAAGGTTCTGGAAAGAGA (SEQ ID NO: 3);
TGTAGGTCACCTGAGTGTGA (SEQ ID NO: 4);
GCTGCACCCAGGGGATCCAT (SEQ ID NO: 5);
TCTCGTAGTTGCTTCTGCTG (SEQ ID NO: 6);
GAGCGAGGCCGCAGCGTCTC (SEQ ID NO: 7);
ATCAGCCAGAACCATCACTC (SEQ ID NO: 8);
ACCTGTACCCTATAAGTGGT (SEQ ID NO: 9);
GATAACTTACCTGGAGAGGC (SEQ ID NO: 10);
TTAGGGTTGGACATGATATC (SEQ ID NO: 11);
CCCACTCCTGCAGGGCAGTG (SEQ ID NO: 12);
GGGTCTTCACCACTGGAGAG (SEQ ID NO: 13);
AGTGAAAAGGCTGACCTGAA (SEQ ID NO: 14);
TGGATGCCCGTGACACTGGG (SEQ ID NO: 15);
GCCGGGCCCAGGGGATCCAT (SEQ ID NO: 16);
CACCCAGATCCAGCGTCCCA (SEQ ID NO: 17);
ATCTCCTGACCTTGTGATCC (SEQ ID NO: 18);
GATCTCCTGACCTAGGAAGA (SEQ ID NO: 19);
TTCTCACTCAGTTGGCCCAT (SEQ ID NO: 20);
CCAACCACCACACCTGTCAT (SEQ ID NO: 21);
GGACGAGTAACAGCTGGATT (SEQ ID NO: 22);
GCTTGGCTGCACCCAGGGGATC (SEQ ID NO: 23);
CTCTGCCGCTCCTGGACACTGCTGC (SEQ ID NO: 24);

13. A nucleic acid according to claim 12, wherein said nucleic acid is selected from the group consisting of DNA and RNA.

14. A vector that contains and expresses a nucleic acid according to claim 12.

15. A pharmaceutical formulation comprising a vector according to claim 14 in a pharmaceutically acceptable carrier.

16. A method of treating a subject afflicted with cancer, comprising administering to said subject a vector according to claim 14 in an amount effective to treat said cancer.

17. A method according to claim 16, wherein said cancer is a carcinoma.

18. A method according to claim 16, wherein said cancer is selected from the group consisting of colon, pancreatic, ovarian, gastric, breast, lung, hepatocellular, prostate, bladder, renal, and uterine cancer.

19. A cell that contains and expresses a nucleic acid according to claim 12.

20. An oligonucleotide according to claim having the sequence: GCTTGGCTGCACCCAGGGGATC (SEQ ID NO: 23)(FUT3 3.5).

21. An oligonucleotide according to claim 1 having the sequence: CTCTGCCGCTCCTGGACACTGCTGC (SEQ ID NO: 24)(FUT 6 LEADER).

and continuous 15 or 18 nucleotide fragments of the sequences listed above in an amount effective to treat said cancer.

Please add Claim 22:

22. (New) A method according to claim 9, wherein said olgionucleotide does not activate RNase H.